K080120

510(K) SUMMARY

MAR 10 2008

This summary is being submitted in accordance with 21 CFR 807.92.

1. GENERERAL INFORMATION

1.1. Submitter Information

Manufacturer's Name:	Philips Medical Systems MR Technologies Finland Oy
Address:	Ayrities 4 PO Box 185 FIN-01510 Vantaa FINLAND
Establishment Registration #	9680194

1.2. Contact Person Name and Information

Contact:	Catherine M. Connell
Title:	Quality & Regulatory Engineer
Company:	Philips Medical Systems (Cleveland), Inc.
Address:	595 Miner Road Cleveland, OH 44143 OH
Telephone #	(440) 483-5581
Facsimile #:	(440) 483-2648
E-mail:	catherine.connell@philips.com

1.3. Trade name and common name of device

Trade name:	HFO Shoulder Coil
Common name:	Magnetic resonance specialty Coil

1.4. Classification of the device

Classification:	Coil, Magnetic Resonance, Specialty
Regulation:	21 CFR 892.1000
Class:	Class II
Procode:	MOS

1.5. Predicate Device`

Invivo Corporation
Shoulder Array Coil Set QSC-127-INT
(K040288)

2. BASIS FOR SUBSTANTIAL EQUIVALENCE DETERMINATION

2.1. Device Description

The HFO Shoulder Coil consists of a cup-shaped, plastic enclosure containing three coil elements for receiving of RF signals from the shoulder and adjacent region. The enclosure is placed on patient's shoulder for imaging. The enclosure contains tuning and decoupling electronics circuitry and preamplifiers. The coil enclosure has a cable attached to it and the cable connector is plugged into the system connector on the patient table. The cable provides the coil with supply and control voltages and transfers the received RF signals to the system. The cable connector contains coil interface circuitry for the system.

2.2. Intended use

The addition of the HFO Shoulder Coil does not change the existing indications for use of the cleared High Field Open (1.0T) Panorama system, as defined below.
The High Field Open (1.0T) Panorama system is indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2), and (3) display the soft tissue structure of the head, extremities and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

The HFO Shoulder Coil is indicated for use in the following anatomic regions and with the designated nuclei:

Anatomic Region:	Shoulder and adjacent regions
Nuclei Excited:	Hydrogen

2.3. Safety Information

The use of the HFO Shoulder Coil does not result in any changes to the safety specifications for the safety parameters (i.e., static field, time-varying magnetic fields, SAR, or acoustic noise) of the Philips HFO (1.0T) Panorama system. The use of this device does not result in additional potential hazards when compared to currently marketed, receive-only coils.

2.4. Conclusion

The HFO Shoulder Coil is substantially equivalent to the Invivo Corporation Shoulder Array Coil Set QSC-127-INT.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Philips Medical Systems MR Finland
% Ms. Catherine Connell
Quality & Regulatory Engineer
Philips Medical Systems (Cleveland), Inc.
595 Miner Road
CLEVELAND OH 44143

MAR 10 2008

Re: K080120
Trade/Device Name: HFO Shoulder Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: January 4, 2008
Received: January 17, 2008

Dear Ms. Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K080120

Device Name: HFO Shoulder Coil

Indications for Use:

The HFO Shoulder Coil is indicated for use in the following anatomic regions and with the designated nuclei:

Anatomic Region:	Shoulder and adjacent regions
Nuclei Excited:	Hydrogen

The addition of the HFO Shoulder Coil does not change the existing indications for use of the cleared High Field Open (1.0T) Panorama system, as defined below.

The High Field Open (1.0T) Panorama system is indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2), and (3) display the soft tissue structure of the head, extremities and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080120